

**REMARKS/ARGUMENTS**

Entry of the present amendment is respectfully requested. By the present amendment, claim 78 has been amended to better emphasize the patentable distinctiveness of the claim. Claims 78-90 remain pending in the application.

**I. Substance of Interview**

The applicants' representative would like to express appreciation for the courtesy extended by the Examiner in the telephonic interview of September 13. The rejection of claim 78 under 35 U.S.C. §112 was discussed, and proposed language for clarifying the scope of the claim was agreed upon.

**II. Rejection of claims 78-90 under 35 U.S.C. §112**

Claim 78 has been amended to clarify the intended scope of the claim. Specifically, the phrase "remote from the body" has been replaced with "outside of the body" and it has been clarified that the telemetric device is located inside of a living being. It is respectfully requested that this amendment be entered, as it, to the best of present understanding, will overcome the rejection under 35 U.S.C. §112 and thus places the application in better condition for further consideration. It is respectfully submitted that this amendment could not have been presented earlier, as it is intended to be responsive to the 35 U.S.C. §112 rejection entered in the final rejection. Further, it is respectfully submitted that the amendment will not raise any new issues or require a new search.

**III. Rejection of claims 78-80, 82-86, and 90 under 35 U.S.C. §102**

Claims 78-80, 82-86, and 90 have been rejected as anticipated by U.S. Patent 6,447,448 to Ishikawa et al (hereinafter: Ishikawa). Claim 78, as amended, recites an apparatus for providing an *in vivo* assessment of loads on adjacent bones within a living being. A body is provided for insertion between the adjacent bones. A

first sensor assembly is located within said body. The first sensor assembly generates an output signal in response to and indicative of a load being applied to said body through the adjacent bones. At least one telemetric device is located outside of the body, but within the living being. The at least one telemetric device is operable to receive said output signal from said first sensor assembly and to transmit an EMF signal dependent upon said output signal.

Ishikawa teaches implantable sensors comprising either a spherical ball or a cluster of spherical balls. It will be appreciated that all of the functionality of an Ishikawa device is located within a given sphere or cluster of spheres. When the Ishikawa device is inserted in a location for monitoring, the various sensors, power source, and telemetry are all located within the monitored region. The Office Action cites a portion of Ishikawa (Col. 9, lines 54-61) describing the use of one or more sensors within an artificial disk as a teaching of a body for insertion between the adjacent bones. It will be appreciated, however, if an artificial disk containing one or more sensors represents a body for insertion between adjacent bones, there is no teaching of one telemetric device, outside of the body, but within a living being that is operative to receive an output signal from the sensors and to transmit an EMF signal dependent upon the signal, as recited in claim 78. Accordingly, it is respectfully submitted that Ishikawa does not teach all of the elements recited in claim 78, and the withdrawal of the rejection of claim 78 is respectfully requested.

Turning to the dependent claims, each of claims 79, 80, 82-86, and 90 contain unique elements that, in combination with claim 78, define over the cited art. In the interest of brevity, not all of these dependent claims will be discussed herein, but it is respectfully submitted that each of the claims are patentable over the cited art both for its unique elements and for the reasons discussed with respect to claim 78.

Claim 82, which depends from claim 80 recites, a system in which the first sensor assembly is maintained in physical communication with an interior surface of the body. It is respectfully submitted that Ishikawa does not teach a system in which a sensor is maintained in physical communication with an interior surface of a body. If the artificial disk of Ishikawa is read as the recited body, there is no teaching of affixing the spherical sensor to the interior surface of the disk upon implantation. If the spherical sensor is read as the recited body, it is clear that the sensor is on the exterior surface from FIG. 1 and the description of the sensors. Further, there would seem to be little reason to monitor the interior of the sphere. It is thus respectfully requested that the rejection of claim 82 be withdrawn.

Claim 83, which depends from claim 78, recites an implant associated with the adjacent bones that is external to said body. Ishikawa does not teach an implant associated with the adjacent bones that is external to the inserted body. As recited in claim 78, the first sensor assembly is located within the body. The spherical sensors have their sensors on an exterior surface, as discussed above, and cannot be read as the body. If the artificial disk is read as the body, there is no additional implant taught in Ishikawa. It is thus respectfully requested that the rejection of claim 83 be withdrawn.

Claim 86, which depends from claim 83, recites at least one telemetric device is located on the implant. Ishikawa teaches placing telemetry on the spherical sensors, which are located inside the recited body and this cannot be the implant that is external to the body. There is no teaching in Ishikawa of placing the telemetry at any other location that could be read as the implant recited in claim 83. It is thus respectfully requested that the rejection of claim 86 be withdrawn.

**IV. Rejection of claims 81 and 87-89 under 35 U.S.C. §103**

Claims 81 and 87 have been rejected as being unpatentable over Ishikawa in view of U.S. Published Patent Application 2002/0010390 to Guice et al (hereinafter Guice). Claims 88 and 89 are rejected as unpatentable over Ishikawa in view of Guice and further in view of U.S. Patent 5,925,552 to Keogh et al. It is respectfully submitted that each of these claims are patentable for at least the reasons described above with respect to claim 78.

Claim 81, which depends from claim 80, recites that the second sensor assembly, which includes the at least one telemetric device, is operatively connected to said first sensor via a tube. Claim 87, which depends from claim 86, recited that the at least one telemetric device is operatively connected to the first sensor via a tube such that the first sensor assembly is positioned inside a first end of the tube and a second end of the tube is attached to said implant.

The Office Action states that Ishikawa does not teach a tube connecting a sensor to a telemetric device, as recited in claims 81 and 87, and relies on Guice to provide the required teaching, specifically paragraph 190 of Guice. It is respectfully submitted, however, that Guice does not contain this teaching. The cited paragraph discusses a tool for implanting an implantable sensor into livestock. The sensors can be loaded into a tube (or provided pre-loaded in the tube) and the tube is connected to the installation tool. The sensors are injected through the tube, but the tube itself is discarded. Accordingly, it is respectfully submitted that the tube of Guice cannot represent the recited tube, as it does not connect a sensor to an implant.

Even with a generous reading of the claims, the sensor must be inside of a body implanted between two bones. But once a sensor is implanted in Guice, the

implantation tool is withdrawn, so it could not be connected to such a sensor. The tube of Guice would therefore not provide a suggestion to one skilled in the art to modify the Ishikawa reference to provide the system recited in claims 81 and 87. At best, one skilled in the art might utilize the implantation method with the more compact Ishikawa sensors, but the resulting process would not read on claims 81 and 87. It is thus respectfully submitted that claims 81 and 87 define over the cited art.

In light of the amendment and remarks above, it is submitted that claims 78-90 are allowable over the cited art. Allowance of the subject application is respectfully requested.

Please charge any deficiency or credit any overpayment in the fees for this matter to our Deposit Account No. 20-0090.

Respectfully submitted,



---

Brian W. Bolinger  
Reg. No. 47,434

TAROLLI, SUNDHEIM, COVELL,  
& TUMMINO L.L.P.  
1300 East Ninth Street, Suite 1700  
Cleveland, OH 44114  
Phone: (216) 621-2234  
Fax: (216) 621-4072  
Customer No.: 26,294